

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1.-29. (Canceled).

30. (Currently Amended) ~~A~~An oral pharmaceutical composition comprising a mixture of:

- (a) ~~an active macromolecular principle~~a polypeptide or protein, and
- (b) an aromatic alcohol absorption enhancer chosen from butylated hydroxy toluene,

butylated hydroxy anisole and analogues and derivatives thereof, wherein the aromatic alcohol absorption enhancer is present in an amount by weight greater than or equal to that of the ~~active macromolecular principle~~polypeptide or protein, wherein the composition is coated with an enteric coating which becomes permeable at a pH of from 3 to 7.

31. (Currently Amended) ~~A~~An oral pharmaceutical composition comprising a mixture of:

- (a) ~~an active macromolecular principle~~a polypeptide or protein,
- (b) an aromatic alcohol absorption enhancer chosen from propyl gallate, butylated hydroxy toluene, butylated hydroxy anisole and analogues and derivatives thereof, wherein the aromatic alcohol absorption enhancer is present in an amount by weight greater than or equal to that of the ~~active macromolecular principle~~polypeptide or protein, and
- (c) a solubilization aid capable of increasing the solubility of the aromatic alcohol absorption enhancer in aqueous media, wherein the composition is coated with an enteric coating which becomes permeable at a pH of from 3 to 7.

32. (Previously Presented) A composition according to claim 30, wherein the mixture comprises less than 5% by weight of water.

33. (Canceled).

34. (Previously Presented) A composition according to claim 30, wherein the mixture comprises at least 1% by weight of the aromatic alcohol absorption enhancer.

35. (Currently Amended) A composition according to claim 30, wherein the ratio by weight of the aromatic alcohol absorption enhancer to ~~active macromolecular principle polypeptide or protein~~ is at least 5:1.

36. (Previously Presented) A composition according to claim 30, wherein the mixture is in the form of a solution or a microparticulate dispersion.

37. (Previously Presented) A composition according to claim 30, wherein the mixture is in solid form.

38. (Canceled).

39. (Currently Amended) A composition according to claim 30, wherein the aromatic alcohol absorption enhancer is chosen from BHT, BHA and analogues and derivatives ~~thereof, including analogues and derivatives~~ of hydroxy toluene or hydroxy anisole where the methyl group or the methoxy group linked to the aromatic ring and/or the hydrogen ortho to the hydroxyl group are replaced by linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl, either unsubstituted or substituted in any position, ~~especially by~~ halogen atoms.

40. (Currently Amended) A composition according to claim 31, wherein the aromatic alcohol absorption enhancer is propyl gallate or ~~an analogue or a derivative thereof, including~~

~~esters of gallic acid, where the esters may be linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl ester~~~~ester~~ of gallic acid, and the compounds are optionally substituted with halogen atoms, linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl esters.

41. (Previously Presented) A composition according to claim 31, where the solubilization aid is chosen from a bile acid or salt, benzyl alcohol, phenyl ethanol, phenoxyethanol, transcutol and isopropanol.

42. (Currently Amended) A composition according to claim 30, where the ~~active macromolecular principle~~polypeptide or protein is insulin, calcitonin, growth hormone, parathyroid hormone, or erythropoeitin, and derivatives and analogues, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

43. (Currently Amended) A composition according to claim 30, where the ~~active macromolecular principle~~polypeptide or protein is insulin, calcitonin, parathyroid hormone or a derivative or an analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

44. (Currently Amended) A composition according to claim 43, where the ~~active macromolecular principle~~polypeptide or protein is insulin or a derivative or an analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin and the composition further comprises an insulin sensitizing agent.

45. (Canceled).

46. (Currently Amended) A method of enhancing the absorption of ~~an active macromolecular principle~~a polypeptide or protein in a patient, which method comprises orally administering to said patient a composition as defined in claim 30.

47. (Currently Amended) A method according to claim 46 wherein the composition enhances the absorption of a ~~macromolecule~~polypeptide or protein across the intestinal wall.

48. (Currently Amended) A method of enhancing the absorption of ~~an active~~
~~macromolecular principle~~a polypeptide or protein in a patient, which method comprises orally administering to said patient an aromatic alcohol chosen from propyl gallate, butylated hydroxy toluene, butylated hydroxy anisole and analogues and derivatives thereof together with a solubilization aid capable of increasing the solubility of the aromatic alcohol absorption enhancer in aqueous media.

49. (Previously Presented) A method according to claim 47, wherein the composition comprises less than 5% by weight of water.

50. (Previously Presented) A method according to claim 48, wherein the solubilization aid is selected from a conjugated bile acid or salt, benzylalcohol, phenylethanol, phenoxyethanol, transcutol and isopropanol.

51. (Previously Presented) A method according to claim 47, wherein the composition is comprised in a medicament, which medicament is provided in the form of a solution, as a microparticulate dispersion or as a solid.

52. (Canceled).

53. (Currently Amended) A method according to claim ~~52~~48, wherein the ~~macromolecule~~polypeptide or protein to be absorbed/~~active~~macromolecular principle to be absorbed is selected from insulin, calcitonin, growth hormone, parathyroid hormone, and erythropoietin, GLP1 and GCSF, and derivatives and analogues thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

54. (Currently Amended) A method according to claim 53, wherein the ~~macromolecule to be absorbed/active macromolecular principle polypeptide or protein~~ to be absorbed is insulin, calcitonin, parathyroid hormone or a derivative or an analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

55. (Currently Amended) A method according to claim 54, wherein the ~~macromolecular principle polypeptide or protein~~ is insulin or a derivative or an analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin, and an insulin sensitizing agent is also present.

56. (Canceled).

57. (Currently Amended) ~~A~~An oral pharmaceutical composition comprising a mixture of:

- (a) ~~an active macromolecular principle which is a polypeptide or protein, polynucleotide, polysaccharide or a mixture thereof,~~
- (b) an aromatic alcohol absorption enhancer selected from butylated hydroxy toluene, butylated hydroxy anisole and analogues and derivatives ~~thereof, including analogues and derivatives~~ of hydroxy toluene or hydroxy anisole where the methyl group or the methoxy group linked to the aromatic ring and/or the hydrogen ortho to the hydroxyl group are replaced by linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl, either unsubstituted or substituted in any position, ~~especially~~ by halogen atoms, and wherein the aromatic alcohol absorption enhancer is present in an amount by weight greater than or equal to that of the ~~active macromolecular principle polypeptide or protein~~, and
- (c) a solubilization aid capable of increasing the solubility of the aromatic alcohol absorption enhancer in aqueous media, which is chosen from a bile acid or salt, benzyl alcohol, phenyl

ethanol, phenoxyethanol, transcutol and isopropanol, wherein the composition is coated with an enteric coating which becomes permeable at a pH of from 3 to 7.

58. (Currently Amended) ~~A~~An oral pharmaceutical composition comprising a mixture of:

- (a) ~~an active macromolecular principle which is a polypeptide or protein, polynucleotide, polysaccharide or a mixture thereof,~~
- (b) ~~an aromatic alcohol absorption enhancer which is propyl gallate or an analogue or a derivative thereof, including esters of gallic acid, where the esters may be linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl ester~~ester~~ester of gallic acid~~, and the compounds are optionally substituted with halogen, linear or branched chain C₁₋₁₂ alkyl, C₁₋₁₂ alkyloxy, C₁₋₁₂ alkylthio or C₂₋₁₂ alkenyl esters, and wherein the aromatic alcohol absorption enhancer is present in an amount by weight greater than or equal to that of the active macromolecular principlepolypeptide or protein, and
- (c) a solubilization aid capable of increasing the solubility of the aromatic alcohol absorption enhancer in aqueous media, which is selected from a bile acid or salt, benzyl alcohol, phenyl ethanol, phenoxyethanol, transcutol and isopropanol, wherein the composition is coated with an enteric coating which becomes permeable at a pH of from 3 to 7.